



ease



Embargoed until 26 September 2007, 09:00 CET

Basel, 23 September 2007



SUPPL

Herceptin eradicates tumours and may reduce the need for mastectomies in women with inflammatory HER2-positive breast cancer – one of the most aggressive and fastest growing forms of the disease

PROCESSED

OCT 17 2007
THOMSON
FINANCIAL

Barcelona, Spain 26 September 2007 – New data show that the addition of Herceptin (trastuzumab) to chemotherapy prior to breast cancer surgery (neoadjuvant therapy) completely eradicates tumours in nearly three times as many women with inflammatory HER2-positive breast cancer compared to chemotherapy alone. Inflammatory breast cancer is a rare, but highly aggressive form of the disease - the tumours spread quickly, often leading to the need for total mastectomies, and it has a worse outlook than other breast cancers. These results are particularly significant as treatment with Herceptin in this setting may actually lead to more breast conserving surgery and most importantly to potentially improved survival.

“Once again, Herceptin has been shown to deliver meaningful benefits to patients with HER2-positive breast cancer,” said Prof. Dr. med. Wolfgang Eiermann, Medical Director of the Red Cross Women’s Hospital in Munich, Germany. “Herceptin has been proven to extend lives across the spectrum of HER2-positive disease, so these latest findings will be welcome news for the unfortunate few with inflammatory breast cancer, which is an especially devastating form of the disease.”

HER2-positive disease is diagnosed in up to 30% of all breast cancer cases.⁽ⁱ⁾ It demands special attention because the tumours are typically fast-growing and there is a high likelihood of relapse. Neoadjuvant therapy is administered to patients to help make inoperable tumours shrink and become removable, thus promoting breast conserving surgery.

llw
10/15

The results from the NeOAdjuvant Herceptin (NOAH) study demonstrated that Herceptin plus

chemotherapy led to the complete disappearance of the tumour in the breast (a pathological complete response to treatment) in nearly three times as many patients with inflammatory breast cancer (55% vs. 19%, $p=0.004$) compared to chemotherapy alone.^[iii] Furthermore, the combination led to complete disappearance of the tumours from both the breast and the lymph nodes (a total pathological complete response to treatment) in 48% of patients, compared to only 13% of those who received chemotherapy alone ($p=0.002$). The treatment was well tolerated with acceptable cardiac safety. The trial is ongoing and event-free survival data are maturing.

About the NOAH study

NOAH is a phase III trial assessing neoadjuvant Herceptin in combination with chemotherapy in patients with HER2-positive locally advanced breast cancer (LABC). Patients were assigned to one of two cohorts depending on HER2 status. All patients received neoadjuvant chemotherapy before surgery consisting of three cycles of doxorubicin-paclitaxel (AT), four cycles of paclitaxel (T) and three cycles of cyclophosphamide / methotrexate / 5-fluorouracil (CMF). Patients with HER2-positive disease were randomised to receive concomitant Herceptin for one year or chemotherapy only.

Out of 228 evaluable patients with HER2-positive breast cancer that were included in the study, 61 had inflammatory breast cancer (IBC). Of the 99 evaluable patients with HER2-negative breast cancer, 14 had IBC. 31 patients with HER2-positive IBC received Herceptin in addition to chemotherapy.

The NOAH protocol is a joint effort of Fondazione Michelangelo, Gruppo SOLTI and Roche.

About breast cancer

Breast cancer is the most common cancer among women worldwide.^[iii] Each year more than one million new cases of breast cancer are diagnosed worldwide, and nearly 400,000 people will die of the disease annually.^[iv]

In HER2-positive breast cancer, increased quantities of the HER2 protein are present on the surface of the tumour cells. This is known as 'HER2-positivity.' High levels of HER2 are present in a particularly aggressive form of the disease which responds poorly to chemotherapy. Research shows that HER2-positivity affects approximately 20-30 percent of women with breast cancer.

About Herceptin (trastuzumab)

Herceptin is a humanised antibody, designed to target and block the function of HER2, a protein produced by a specific gene with cancer-causing potential. It has demonstrated efficacy in treating

both early and advanced (metastatic) breast cancer. Given on its own as monotherapy as well as in combination with or following standard chemotherapy, Herceptin has been shown to improve response rates, disease-free survival and overall survival while maintaining quality of life in women with HER2-positive breast cancer.

Herceptin received approval for use in the European Union for advanced (metastatic) HER2-positive breast cancer in 2000, and for early HER2-positive breast cancer in 2006. In the advanced setting, Herceptin is now approved for use as a first-line therapy in combination with paclitaxel where anthracyclines are unsuitable, as first-line therapy in combination with docetaxel, and as a single agent in third-line therapy. It is also approved for use in combination with an aromatase inhibitor for the treatment of post-menopausal patients with HER2 and hormone receptor co-positive metastatic breast cancer. In the early setting, Herceptin is approved for use following standard (adjuvant) chemotherapy.

Herceptin is marketed in the United States by Genentech, in Japan by Chugai and internationally by Roche. Since 1998, Herceptin has been used to treat nearly 400,000 HER2-positive breast cancer patients worldwide.

About Roche

Headquartered in Basel, Switzerland, Roche is one of the world's leading research-focused healthcare groups in the fields of pharmaceuticals and diagnostics. As the world's biggest biotech company and an innovator of products and services for the early detection, prevention, diagnosis and treatment of diseases, the Group contributes on a broad range of fronts to improving people's health and quality of life. Roche is the world leader in in-vitro diagnostics and drugs for cancer and transplantation, a market leader in virology and active in other major therapeutic areas such as autoimmune diseases, inflammation, metabolism and central nervous system. In 2006 sales by the Pharmaceuticals Division totaled 33.3 billion Swiss francs, and the Diagnostics Division posted sales of 8.7 billion Swiss francs. Roche employs roughly 75,000 worldwide and has R&D agreements and strategic alliances with numerous partners, including majority ownership interests in Genentech and Chugai. Roche's Diagnostics Division offers a uniquely broad product portfolio and supplies a wide array of innovative testing products and services to researchers, physicians, patients, hospitals and laboratories world-wide. For further information, please visit our website at www.roche.com.

All trademarks used or mentioned in this release are protected by law.

Roche Group Media Office

Phone: +41 61 688 8888 / e-mail: basel.mediaoffice@roche.com

- Daniel Piller (Head of Roche Group Media Office)
- Baschi Dürr
- Martina Rupp
- Claudia Schmitt

^[i] Harries M, Smith I. The development and clinical use of trastuzumab (Herceptin). *Endocr Relat Cancer* 9: 75-85, 2002.

^[ii] Baselga J, et al., Efficacy of Neoadjuvant Trastuzumab in Patients With Inflammatory Breast Cancer: Data From the NOAH (NEOADJUVANT HERCEPTIN) Phase III Trial. Abstract #2030. ECCO Meeting 2007.

^[iii] World Health Organization, <http://www.who.int/cancer/detection/breastcancer/en/>

^[iv] Ferlay J, et al., GLOBOCAN 2002. Cancer Incidence, Mortality and Prevalence Worldwide. IARC CancerBase No.5, Version 2.0. IARCPress, Lyon, 2004. 2004

END